

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

IN RE: SUBPOENAS TO NON-PARTIES
KALEIDA HEALTH AND BUFFALO
GENERAL MEDICAL CENTER,

Respondents.

PROGRESSIVE STERILIZATION, LLC,
PMBS, LLC,
Petitioners/Plaintiffs,

v.

TURBETT SURGICAL, LLC.
TURBETT SURGICAL, INC.,

Defendants.

**DECISION
and
ORDER**

21-MC-34V(F)

APPEARANCES:

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By papers filed July 9, 2021 (Dkt. 1) ("Rule 45 ___"), Petitioners move, pursuant to Fed.R.Civ.P. 37(1)(2), to compel Respondents' compliance with Petitioners' subpoena *duces tecum* pursuant to Fed.R.Civ.P. 45(a)(1), served February 10, 2021 ("Petitioners' subpoena" or "the subpoena"), in connection with the underlying patent infringement and false advertising action pending in the District of Delaware (19-CV-627-CFC D.Del.) ("Petitioners' motion"). In opposition, Respondents, on July 21, 2021, filed Respondents' Cross-Motion For Full Reimbursement of Costs [...] Attorneys Fees and For a Protective Order (Dkt. 9, 9-1, 9-14). Respondents' Reply was filed August 3, 2021 (Dkt. 14). The matter was referred to the undersigned by Hon. Lawrence J. Vilardo on July 14, 2021 (Dkt. 5). A motion to compel discovery is non-dispositive, see *Cайдор v. Онондага Кантри*, 517 F.3d 601, 604 (2d Cir. 2008); motions for a protective order and to quash a Rule 45 subpoena are also non-dispositive. *Ergas v. Eastpoint Recovery Group, Inc.*, 2021 WL 1711321, at * 1 n. 1 (W.D.N.Y. Apr. 30, 2021) (citing *Cайдор*, 517 F.3d at 602-04).

Petitioners' Rule 45 subpoena requests information for a period commencing January 1, 2015 pertaining to Respondents' use of the accused surgical sterilization device manufactured by Defendant and a study conducted and published by one Dr. Brian McGrath, an orthopedic surgeon on the staff of Respondent Buffalo General Hospital with the alleged assistance of certain of Buffalo General Hospital staff members ("the McGrath Study"). Respondent Kaleida Health ("Kaleida"), a New York not-for-profit corporation, is an amalgamation of several major regional health care facilities including Respondent Buffalo General Hospital, providing comprehensive medical services. Respondents have produced a substantial amount of documents

responsive to Petitioners' subpoena except for 6,655 e-mails which Respondents identified ("the e-mails") but have refused to produce in the absence of an acceptable agreement for reimbursement by Petitioners of Respondents' expenses incurred in responding to the subpoena including Respondents' insistence that counsel review each e-mail to assure it is in fact responsive to the subpoena and to minimize by redaction unnecessary production of protected health information ("PHI") as required by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as applicable to Respondents.

Respondents' cross-motion for a protective order is directed to Petitioners' Deposition Notice, served on June 3, 2021, pursuant to Fed.R.Civ.P. 30(b)(6) ("Rule 30(b)(6)'), to answer Petitioners' questions regarding Respondent Kaleida's response to Petitioners' subpoena. At the time of Petitioners' motion, Petitioners had proposed to reimburse Respondents for expenses in the amount of \$6,000 incurred in identifying and retrieving the responsive e-mails; Respondents, however, demanded \$7,500. Petitioners also offered to reimburse Respondents 33 1/3% of the costs of Respondents' review of the e-mails prior to submitting them to Petitioners, estimated by Respondents to be in the range of \$10,000 to \$14,000, but contending such pre-response review was not required; Respondents demanded 80% reimbursement for this cost. Petitioners and Respondents also had agreed upon the terms of a Qualified Protective Order ("QPO"), as defined by 45 C.F.R. § 164.512(e)(1)(v), except for reimbursement of Respondents' costs, whether this court could approve the QPO and the need for the Rule 30(b)(6) deposition of Kaleida's representation thus leading to the instant motions.

Generally, a non-party responding to a Rule 45 subpoena is expected to shoulder its costs incurred in compliance with the subpoena unless the costs constitute an “undue burden” upon the non-party. See *Nike, Inc. v. Wu*, 2020 WL 257475, at *11 (S.D.N.Y. Jan. 17, 2020) (citing caselaw). Where electronically stored information, such as e-mails, is involved, the court should protect the non-party against “significant expense” associated with compliance. *Id.* (referencing Rule 45(d)(2)(B)(ii)). Here, Respondents do not contend they incurred significant expenses in the course of e-mail identification through use of agreed search terms and to reduce the number of 70,000 so identified hits to the 6,655 e-mails that are apparently responsive to the subpoena. Respondents’ stated cost of \$9,000 for such activity does not, in context, appear to qualify as a significant expense and Respondents do not argue that it is. See Dkt. 14-1 at 7 (“Kaleida’s motion is . . . about expense *to be incurred* in reviewing the . . . emails . . .”) (italics in original). Whether a non-party will nevertheless suffer an “undue burden” absent cost-shifting ordered by the court turns on the relevance of the requesting party’s need for the documents, the breadth of the request, the time period covered by the request, the burden actually imposed, and the actual expense of the responding party. *In Re Novartis and Par Antitrust Litig.*, 2020 WL 3317203, at *5 (S.D.N.Y. June 18, 2020). Here, Respondents do not dispute the subpoena requests relevant information, nor do Respondents argue the subpoena’s requests are overly broad; rather, as noted, Respondents contend undue burden arises from the expenses that will be incurred by Respondents for services in responding to the subpoena and a pre-release review of the e-mails to comply with HIPAA requirements the violation of which will expose Kaleida to the risk of substantial penalties. See Dkt. 14 at 7-8. Cost shifting depends

upon weighing equitable factors such as whether the non-party has an interest in the underlying case, whether the non-party can more readily bear the costs of compliance compared to that of the requesting party, and whether the litigation is of public import.

Nike, Inc., 2020 WL 257474, at *11 (citing *Honeywell Intern., Inc. Sec. Litig.*, 203 F.R.D. 293, 302-03 (S.D.N.Y. 2003)). The protection afforded to a responding non-party by Rule 45 does not, however, require full cost-shifting. *Nike, Inc.*, 2020 WL 257475, at *11 (quoting *Honeywell Intern., Inc. Sec. Litig.*, 203 F.R.D. at 302-03). The party seeking cost-shifting and a protective order bears the burden of establishing the need for such relief. See *In re Novartis and Par Antitrust Litigation*, 2020 WL 3317203, at * 5-6. Granting any such protection to a responding non-party is within the court’s “broad discretion.” *In Re Novartis and Par Antitrust Litig.*, 2020 WL 3317203, at *5 (quoting *Mackey v. IDT Energy, Inc.*, 2019 WL 2004280, at *3 (S.D.N.Y. May 7, 2019)). Here, the court finds all three factors support Petitioners’ motion and require denial of Respondents’ cross-motion for full reimbursement.

First, although Respondents have, at present, no apparent direct financial interest in the underlying infringement and false advertising case, yet Dr. McGrath, author of the McGrath Study which allegedly promoted the advantages of Defendants’ accused product, is alleged to be an investor in Defendants’ accused product and his “study,” prepared with the assistance of three Kaleida staff members, was based on 2,100 orthopedic surgeries Dr. McGrath performed at Respondent Buffalo General Hospital. Moreover, Kaleida, according to the record, has purchased a number of the Defendants’ accused devices for use in its hospitals which devices allegedly are more efficient in sterilization of surgical instruments. Thus, Respondents cannot be said to be

at completely ‘arms-length’ with respect to the underlying litigation; it is also unrealistic to believe that Respondents lack any interest in whether a prominent member of its surgical staff has invested in and promoted the purchase by Kaleida of devices infringing on a valid patent and engaged in false advertising based on their use at one of Respondent Kaleida’s largest facilities as Petitioners claim in the underlying action. Second, the record, see Dkt. 1 at 15 (website information), indicates Respondent Kaleida has annual revenues of approximately \$1.8 billion; in contrast, Petitioners’ combined revenues are approximately \$1.65 million. While Kaleida attempts to minimize this financial disparity by asserting it has recently suffered operating losses, Dkt. 9-14 at 14-15, yet Respondents do not suggest Kaleida has experienced less than positive cash flow sufficient to meet payroll and other expenses such as payment of the Kaleida’s attorneys’ fees for this matter. Third, whether the accused devices, important appurtenances used in performing major surgeries in the hospitals, are in fact infringing valid patents and promoted as a result of false advertising, given that substantial payments for the medical services provided by Kaleida like other hospitals are from public sources, e.g., Medicare, certainly presents a matter of significant public concern. Thus, all three relevant factors support a denial of any cost-shifting to Petitioners for Respondents’ compliance with the subpoena in this case even assuming the actual amounts incurred by Respondents, in responding to the subpoena, are as large – \$40,000 in legal fees plus \$10,000 in retrieving relevant ESI – as Respondents assert (Dkt. 9-1 at 9). Nor is the fact, as Respondents argue, Dkt. 9-14 at 9, that Petitioners recently changed course, for a brief period, regarding possible review of the e-mails by proposing a search by Petitioners at .pers’ expense of Respondent Buffalo General’s

surgical records to obtain the information (presumably relating to the alleged greater efficiency and related issues in the actual use of Defendants' infringing product) sought by the subpoena, instead of Respondents only producing the e-mails, reason to impose Kaleida's compliance costs on Petitioners; such changes in discovery options are common in complex litigation and are to be expected. Additionally, Respondents' contention ignores that it was Kaleida's insistence that it would, notwithstanding Petitioners' inspection, also conduct a prescreening redaction review of the e-mails and seek reimbursement of the associated costs from Petitioners that compelled Petitioners to revert to obtaining the e-mails as Petitioners' preferred and less labor intensive to Petitioners discovery option. See Dkt. 12 at 10. In the circumstances, Petitioners' 'switch' in discovery directed to the e-mails hardly demonstrates litigation misconduct warranting any cost-shifting.

Moreover, the projected costs to Respondents for pre-response screening the e-mails to assure compliance, as Respondents assert with 45 C.F.R. § 164.514(d)(3) and 164.502(b)(1), requiring minimum disclosure of protected health information in particular circumstances, even if required, is not unduly burdensome as these expenses are necessarily part of Respondents' day-to-day operating costs required to be incurred to assure Respondents' full compliance with HIPAA requirements in responding to discovery requests of the kind at issue in this case. However, such pre-response screening by Respondents is not prerequisite to HIPAA compliance because, as noted, a Qualified Protective Order ("QPO"), as defined in 45 C.F.R. § 164.512(e)(1)(v) ("§ 164.512(e)(1)(v)"), sufficient to permit Respondents' full compliance with the subpoena, has been prepared and agreed upon by Petitioners and Respondents (except for the

cost-shifting at issue) in accordance with 45 C.F.R. § 164.512(e)(1)(ii) (“§ 164.512(e)(1)(ii)”), which authorizes release of the HIPAA covered records which may contain PHI, in response to a subpoena as in the instant case where a QPO has been sought as provided by 45 C.F.R. § 164.512(e)(1)(iv), and needs only court approval to come into full effect. Respondents contend that because Petitioners’ subpoena does not explicitly seek PHI that may be contained in the e-mails, pre-release screening and redaction by Kaleida is nevertheless required by HIPAA, specifically, 45 C.F.R. §§ 164.502(b)(1) (“§§ 164.502(b)(1)”) and 164.514(d)(3) (“164.514(d)(3)”). See Dkt. 9-14 at 16 n. 5. However, as the subpoena and putative Qualified Protective Order are squarely within the scope of the exemption for disclosure of PHI provided by §§ 164.512(e)(1)(ii) and (v), permitting full compliance with the subpoena by Respondents, any incidental disclosure of PHI which may be lodged in the e-mails is also fully protected as HIPAA requires; Respondents cite no definitive authority to the contrary and at least two cases hold otherwise. See *Ruggles v. WellPoint, Inc.*, 2010 WL 11570681, at **14, 15 (N.D.N.Y. Dec. 28, 2010) (“[N]either HIPAA nor its rules and regulations impeded the disclosure of non-parties’ personal health information when protected by a court order; rather it permits such disclosure) (citing *Lowe v. Vadlamudi*, 2010 WL 2474808 (E.D. Mich. June 4, 2010)); *United States v. W.R. Grace*, 401 F.Supp.2d 1093, 1101 (D.Mont. 2005) (“Neither the testifying witnesses’ privacy rights nor the applicable statutes (HIPAA and the Privacy Act, both of which allow disclosure subject to a protective order) require the redaction of medical records before disclosure). Additional protection to Respondents for inadvertent disclosure of non-responsive PHI may also be included in the QPO as a claw-back provision. See

Ruggles, 2010 WL 11570681, at *17 (citing 45 C.F.R. § 164.512(e)(v)(B)) (requiring QPO to mandate return or destruction of PHI at conclusion of litigation). That further pre-release screening by Respondents, in accordance with §§ 164.502(b)(1), 164.514(d)(3) as Respondents insist, of the e-mails to assure PHI is not unnecessarily disclosed is not required to comply with the subpoena is also supported by the fact that in none of the other categories of exempt disclosures permitted by § 164.512(b)-(d), (e)-(l), e.g., § 164.512(f) (authorizing release of protected health information for law enforcement purposes), is there any requirement of a QPO which assures the privacy protections required by HIPAA for PHI are satisfied thus arguably warranting in those exemption categories the minimization required by § 164.502(b)(1) and § 164.514(d)(3) Respondents believe is required in the instant matter. However, as noted, in the case of a litigation subpoena, like the one in this case, pursuant to § 164.512(e)(i)(ii), full release in response to the subpoena is conditioned only on the existence of a QPO like the one available here. See *Ruggles*, 2010 WL 11570681, ** 14, 15; *W.R. Grace*, 401 F.Supp.2d at 1101.

Although Petitioners contend the undersigned should approve the proposed order, the court finds it lacks authority to do so as, according to 45 C.F.R. § 164.512(e)(1)(iv)(A), the Qualified Protective Order must be approved by the court with jurisdiction over the underlying “dispute,” i.e., the litigation in which the PHI may be utilized subject to the QPO by the parties in the litigation. In this instance, that is the District Court of Delaware, not this court. Thus, upon submission for approval of the proposed Qualified Protective Order conforming to § 164.512(e)(1)(v) to the Delaware District Court, Respondents have no justification based on HIPAA prerequisites to

refuse compliance with the subpoena for access to the e-mails at issue here, nor to cost-shift Respondents' compliance costs to Petitioners as a condition to providing the e-mails. In Respondents' Reply, Dkt. 14 ¶ 5, in addition to Respondents' contentions based on the asserted need to protect PHI, Respondents also posit the need to screen the e-mails for attorney-client privileged material and information protected by N.Y. Public Health Law § 2805-m relating to a hospital's internal quality control. Respondents' arguments that the e-mails may disclose attorney-client privileged information and information protected from disclosure by other statutes such as N.Y. Pub. Health Law § 2805-m, Dkt. 14-1 at 6-7 and n. 4, were not previously raised in Respondents' initial opposition papers and are thus waived. See *Connecticut Bar Ass'n v. United States*, 620 F.3d 81, 91 n. 13 (2d Cir. 2010) (noting issue raised in district court "for the first time in a reply brief are generally deemed waived." (citing *Norton v. Sam's Club*, 145 F.3d 114, 117 (2d Cir. 1998))). In any event, an agreement pursuant to Fed.R.Evid. 502(d) would provide Respondents with sufficient protection of any privileged material without pre-screening or redaction as Respondents demand. See *Zubulake v. UBS Warburg LLC*, 216 F.R.D. 280, 290 (S.D.N.Y. 2003) (parties may forgo document review for privileged information in reliance on 'claw-back' agreements which require return of inadvertently produced privileged documents).

As regards Petitioners' notice of a Rule 30(b)(6) deposition and Respondents' request for a protective order, while it may be the case, as Respondents contend, that any questions regarding how Respondents conducted their search for information, including ESI responsive to the subpoena, can be obtained from Respondents' counsel who oversaw the search process, nevertheless, Petitioners are entitled to examine

Respondents' representative on the noticed subject area and the court has no reason to conclude, on this record, that Petitioners' notice is in bad faith or constitutes litigation abuse. Further, Respondents do not dispute that requesting parties are entitled to conduct a Rule 30(b)(6) deposition to assure that a non-party respondent has met its obligation to conduct a comprehensive search for all reasonably available responsive documents and information responsive to a Rule 45 subpoena. Respondents' complaint, Dkt. 14-1 at 11-12, that Petitioners to date have failed to particularize the issues Petitioners seek to address is also without merit as such specific questions would likely require exposing Petitioners' work-product to Respondents prior to the deposition. Accordingly, the court declines to grant the protective order barring the Petitioners' Rule 30(b)(6) deposition as Respondents request.

CONCLUSION

Based on the foregoing, Petitioners' motion (Dkt. 1) is GRANTED; Respondents' Cross-Motion (Dkt. 9) is DENIED. The Clerk of Court shall close the file.
SO ORDERED.

/s/ Leslie G. Foschio

LESLIE G. FOSCHIO
UNITED STATES MAGISTRATE JUDGE

Dates: August 4, 2021
Buffalo, New York